REMARKS-GENERAL

1. The Applicant expresses his appreciation to the Examiner for the diligence shown in the examination of this application and for the telephone discussion of 7/7/2004.

2. Reconsideration of the application as amended is respectfully requested.

3. The specification was amended by a replacement paragraph to include a processing element 510 omitted in FIG. 5 of the drawings and to correct a drawing figure number referenced in the specification as originally filed. The Applicant submits that no new matter was introduced as a result of this amendment.

4. FIG. 5 of the drawings was amended to include processing element 510 in the lower part of the sample vessel as disclosed in the specification as originally filed. A proposed drawing change is attached as Exhibit A with the change marked in red. The Applicant submits that no new matter is introduced as a result of this drawing change.

5. Claims 10, 12, 13, 17-22, 26, 27, 29, and 31 have been amended to overcome objections and rejections cited in the office action mailed 4/09/2004, more particularly recite the invention, and to correct editorial errors. These claims are all submitted to be patentable over the cited references because they (1) recite novel structure and thus distinguish physically over every reference (section 102) and (2) the physical distinctions effect new and unexpected results, thereby indicating that the physical distinctions are unobvious under section 103. The Applicant submits that no new matter was introduced as a result of the claim amendments. The current claims of record are claims 10-27 and 29-32.

6. Specifically, claim 13, was rejected under 35 U.S.C. Section 112 as being indefinite since the processing element did not appear in the drawings. FIG. 5 was amended to include the processing element disclosed in the specification as originally filed. In regard to the 35 U.S. C, Section 112 rejection of claims 13 and 22-25, the Applicant submits that

the claims are definite since aperture 215 is not required in the embodiments of the invention as claimed. Independent claims 10 and 21 were amended to more clearly define the fluid communication path in the device. Claims 21, 26, 27, 29 and 31 were amended as suggested by the Examiner to overcome an indefiniteness rejection. Claims 12, 13, 17-19, 22, and 29 were amended to make language consistent with amended claims and better define elements of the claims.

7. Claims 10, 11, 19-21, 26, 27, 29, and 30 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 6,479,298 to Miller et al. Miller et al. discloses a device for separating heavier and lighter fractions of a fluid sample. Centrifugal load is used to deform a seal body to separate the components of the fluid. Claims 21, 26, 27, 29, and 30 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 5,169,602 to Pang et al. Pang et al. discloses a conduit having a funnel-shaped guide, a duckbill valve and a beveled tip. The device is used to add fluid to a closed system with out contamination. Claims 22-25 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 5,169,602 to Pang et al. in view of US Patent 5,945, 070 to Kath et al. Kath et al. discloses a filter tube for a fluid vessel. The device utilizes a filter sipper tube and transfer probe for use in a septum-sealed vessel.

8. Claims 11and 26 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 6,479,298 to Miller et al. in view of US Patent 6,251, 343 to Dubrow et al. Dubrow et al. discloses a body structure having a plurality of ports disposed in a body structure where each port is in fluid communication with one or more channels in a channel network. Claims 12, 17, 18 and 32 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 6,479,298 to Miller et al. or US Patent 5,169,602 to Pang et al. in view of US patent 6,083,761 to Kedar et al. and/or US Patent 4,787,971 to Donald. Kedar et al. disclose a multi-well plate having wells with a capillary hole adapted to retain liquid in the well. Donald discloses a miniature column chromatography apparatus having a multi-stage separation tube and a non-vented cap.

The Novel Physical Features Of The Claims, As Amended, Provide New and Unexpected Results And Hence Should be Considered Unobvious, Making the Claims Patentable Under Section 103.

9. In regards to the obviousness rejections over Miller et al. of independent claim 11, the cited and relied upon Miller et al. reference neither teaches nor suggests a capability of axial alignment of the insert and the needle by insertion of the needle to sufficient depth in the reduced-diameter portion. As shown in FIG. 9, the insert passage is used only as a means of conveyance for the blood sample into the bottom of tube 130 and the needle is not inserted into the reduced diameter portion. In regards to independent claim 21, Miller et al. neither discloses nor suggests moving the device to another processing location by frictional engagement between the needle and septum seal. Rather, the insert of Miller et al. merely repositions within the vessel itself (tube 130) by centrifugal force. In regards to both independent claims 10 and 21, neither does Miller et al. disclose transfer of the sample fluid from the bottom of the vessel, as the tube of Miller et al. comprises a closed end 134.

10. The Applicant disagrees with the Examiner's assertion that it would have been obvious to one having ordinary skill in the art to modify the method of Miller et al. to insert the needle beyond the conical guide into the reduced-diameter portion to "facilitate quicker transfer of liquid into the reduced-volume sample chamber", since the purpose of the insertion into the reduced-diameter portion in the presents invention is to facilitate alignment of the insert to the needle, not increasing the transfer rate. The modifications required to the process of Miller et al. to perform the insert alignment, repositioning of the insert, and fluid transfer functions of the invention as claimed are far too complex to be considered obvious by one of normal skill in the art.

11. In regards to independent claim 21, the cited and relied upon Pang et al. reference neither teaches nor suggests moving the device to another processing location by frictional engagement between the needle and septum seal. Pang et al. does not disclose any method of moving the device to another processing location. Neither does Pang et al.

disclose transfer of the sample fluid from the bottom of the vessel, as the vessel (sample tube 20) of Pang et al. comprises a closed end. The modifications required to the process of Pang et al. to perform the insert alignment, repositioning of the insert, and fluid transfer functions of the invention as claimed are far too complex to be considered obvious by one of normal skill in the art.

Neither the cited and relied upon Kath et al., Dubrow et al., Kedar et al., and Donald references teach or suggest the combination of insertion of a needle into the reduced-diameter portion to a depth sufficient to provide axial alignment of the insert and the needle or movement of the insert to another processing location and transferring fluid through a bottom opening of the vessel.

Unsuggested Combination

12. None of the cited and relied-upon references suggest that the features of the teachings be combined in the dependent claims as suggested by the Examiner.

Multiplicity of Steps Required

13. The combinations, if undertaken, would require a series of separate, awkward combinative steps that are too involved to be considered obvious.

Combination Still Lacking Novel Features

14. Even if the references are combined, the resulting combination would still not result in the present invention. None of the combinations suggested by the Examiner produce a close fit between the needle and the reduced-diameter portion and insertion sufficient for alignment of the needle and the device. Neither do any of the references teach a method of moving the inset to another processing location with the needle. Such features allow

automated handling of the inserts and vessels with fewer steps and lower cost. *None of the references even suggest such an important feature.*

The Cited But Non-Applied References

15. These subsidiary references have been noted and reviewed, but are submitted to be less relevant than the relied upon references.

The Dependent Claims Are A-fortiori Patentable

16. The dependent claims add additional novel features and thus are submitted to be, a-fortiori, patentable.

Allowance Requested

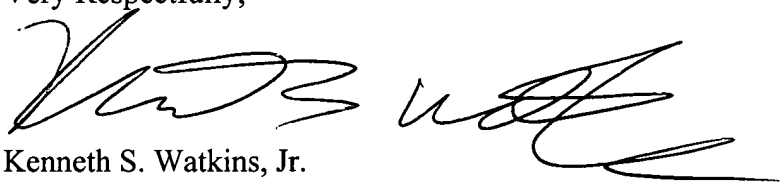
17. For the above reasons, the Applicant submits that the Sample Collection and Processing Device disclosed and claimed in the present application is not taught by any of the references of record, taken either alone, or in combination. Therefore, allowance of the present application is in order and respectfully requested.

Request For Constructive Assistance

The undersigned acknowledges general agreement, conditional upon a supplemental search and review of section 112 issues, that the claims as amended are patentable over the cited art during a telephone discussion with the Examiner on 7/07/2004. If for any reason the claims of this application are not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the

Examiner in order that this application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully,



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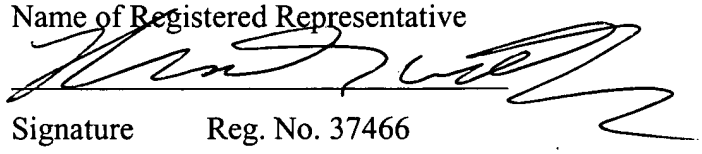

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FIG.5